



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0229]

Use of Rare Pediatric Disease Priority Review Voucher; Approval of a Drug Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the recent approval of a drug product under an application for which the sponsor redeemed a rare pediatric disease priority review voucher. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to redeem priority review vouchers submitted by sponsors of product applications that might otherwise not qualify for priority review. These vouchers entitle the holder of such a voucher to priority review of a single human drug application submitted under the FD&C Act or the Public Health Service Act. FDA has approved PRALUENT (alirocumab), manufactured by Sanofi-Aventis U.S. Inc., under a priority review.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4842, FAX: 301-796-9858, email:

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SUPPLEMENTARY INFORMATION: FDA is announcing the recent approval of a drug product under an application for which the sponsor redeemed a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will grant a priority review for a new drug or biological product application that redeems a priority review voucher, even if that product might not otherwise qualify for a priority review. FDA has recently approved PRALUENT (alirocumab), manufactured by Sanofi-Aventis U.S. Inc., under a priority review. PRALUENT (alirocumab) is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>.

For further information about PRALUENT (alirocumab), go to the Drugs@FDA Web site at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

Dated: August 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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